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Marilyn B. McKenna
Signature

1655 #7
1/15/02

Atty Dkt No. 0300-0014
Affymax No. 2095
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:
Steven E. CWIRLA et al.

Serial No.: 09/620,091 Group Art Unit: 1655

Filing Date: July 20, 2000 Examiner: B. Sisson

Title: COMPOUNDS HAVING AFFINITY FOR THE GRANULOCYTE-COLONY STIMULATING FACTOR RECEPTOR (G-CSFR) AND ASSOCIATED USES

TRANSMITTAL LETTER

Commissioner for Patents
Washington, DC 20231

Sir:

Transmitted herewith for filing are the following documents submitted in Response to the Office Action mailed October 2, 2001:

Response to Requirement for Restriction;

Response to Notice to Comply, including the Sequence Listing in computer readable (disk) and paper forms form and a Statement to Support Filing and Submission in Accordance with 37 C.F.R §§1.821-1.825; and

Change of Address form.

No fee is believed due with this transmittal. If, however, a fee is due the Commissioner is hereby authorized to charge any such fee(s) under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-0580. **A duplicate copy of this sheet is enclosed.**

Respectfully submitted,

Date: 11/2/01 By: Dianne E Reed

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RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to a communication mailed from the PTO on October 2, 2001, requiring restriction. As this response is being mailed within the one-month shortened statutory period, no extension of time is necessary.

THE STATED REQUIREMENT FOR RESTRICTION:

In the Office Action under reply, restriction has been required to one of the following subject matter groupings:

(I) claims 1-16, 23-35, 42-53, 60-67, 74-93, 100-117, 124-140, and 147-155, drawn to a polypeptide compound, and claims 17, 36, 54, 68, 94, 118, 141, and 156, drawn to a pharmaceutical composition comprising the polypeptide; and

(II) claims 18-22, 37-41, 55-59, 69-73, 95-99, 119-123, 142-146, and 157-161, drawn to a method of treatment.

Upon election of Group I or II, applicants have been further required to elect a single sequence.

ELECTION AND REASONS FOR TRAVERSE:

In response, applicants elect Group I and further elect the polypeptide defined by SEQ ID NO 208 with traverse. Traverse with respect to the restriction between individual polypeptides is made on the following grounds.

In making the restriction requirement, the Examiner has alleged that the "sequences are patentably distinct because they are unrelated sequences." See last line on page 2 of the Office Action. Applicants respectfully disagree.

Aside from the fact that all of the claimed polypeptides are functionally related because they are G-CSF modulators, most of the claimed polypeptides (i.e., the polypeptides of SEQ ID NOs. 8-432, 490 and 491) are also structurally related as encompassed by one of seven generic sequences. See claims 1, 23, 42, 60, 74, 101, and 124. That is, seven generic sequences are provided that encompass **all** of the claimed polypeptides except for those set forth in claim 147. Thus, examining all claims as one group, with the possible exception of claims 147 and claims depending therefrom, should be a relatively straightforward matter since a search need only be directed to each of the generic sequences of SEQ ID NOs. 1, 2, 3, 4, 5, 6, and 7 provided in claims 1, 23, 42, 60, 74, 101, and 124, respectively.

On this point, applicants respectfully direct the Examiner's attention to Section 803 of the M.P.E.P., where it is stated that "[i]f a search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits . . ." [emphasis added]. This is true even though an application may include claims to distinct or independent inventions.

In further support of restriction, the Examiner relies upon Section 803.04 of the M.P.E.P. Although the section states that individual sequences are "presumed to represent an independent and distinct invention," this section also states that in order to

> "aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially wave the requirements of 37 C.F.R. §1.141 *et seq*. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction."

Although this section of the M.P.E.P. is directed to nucleotide sequences, applicants assume that the Examiner's reliance on this particular section in the context of applicants' polypeptide sequences is by way of analogy.

Thus, as applicants are entitled to examination of ten sequences, examination of the seven sequences set forth in SEQ ID NOs. 1 through 7 is appropriate and respectfully requested. For all the foregoing reasons, then, applicants request that the Examiner reconsider and withdraw the stated restriction requirement. Should the Examiner decide that some restriction requirement is necessary, applicants suggest an eight-way restriction requirement between SEQ ID NOs. 1 through 7, and the polypeptides of claim 147. The generic sequences clearly demonstrate the relatedness of individual sequences within any one generic sequence. In particular, five out of nine amino acids are conserved in generic SEQ ID NO: 2, three out of six amino acids are conserved in generic SEQ ID NO 3, and five out nine amino acids are conserved in generic SEQ ID NO 4. If the restriction requirement were to be modified in this manner, applicants would then elect the polypeptides defined by SEQ ID NO 5 (claim 74), and, as the ten specific sequences that applicants are entitled to have examined, the ten polypeptides of SEQ ID NOs. 184, 185, 208-213, 323, and 338.

CONCLUSION

In sum, applicants submit that it is straightforward for the claims to be examined as filed, and accordingly request such action by the Office. In the alternative, applicants respectfully request that the restriction requirement be modified as proposed herein.

If the Examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, he is welcome to contact the undersigned attorney at 650-330-0900. Please note that this is a new telephone number, and that all future correspondence concerning this application should be directed to our new address, below.

Respectfully submitted,

Date: 11/2/01 By: Dianne E Reed

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